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Recommendations

- Exclusive breastfeeding is recommended for the first six months of life with sustained breastfeeding for up to two years or longer with appropriate complementary feeding.
- Infant formula should be chosen based on the nutritional requirements and medical needs of an infant when a substitute or supplement for breastmilk is needed.
- Liquid infant formulas (concentrated and ready-to-feed) are sterile until opened and are the safest option for infants requiring formula.
- Powdered Infant Formula (PIF) is not sterile and may be contaminated with pathogens such as Cronobacter (formerly known as Enterobacter sakazakii) or Salmonella enterica.
- When PIF is prepared and handled appropriately it can be safely used for healthy full term infants.
- Until infants are four months of age:
 - All water used to prepare infant formula should be boiled for two minutes.
 - Equipment used to prepare and feed infant formula should be sterilized.
- Liquid infant formulas (concentrated or ready-to-feed) are recommended for infants at the greatest risk of
 infection i.e., pre-term or low-birth weight who are less than two months (postnatal age) or
 immunocompromised. Where nutritionally appropriate liquid infant formula is not available, PIF may be
 recommended by the infant's primary healthcare provider or Registered Dietitian.

Health Benefits

The following document provides specific guidance on the most appropriate way to prepare and handle infant formula to reduce the risk of foodborne illness. Infant formula is an excellent growth medium for bacteria due to its moisture and rich nutrient content.

Considerations

Breastmilk is the only source of nutrition which is required until six months of age. These recommendations are for parents/guardians who have decided not to (or cannot) exclusively breastfeed.

Key Questions

How can infant formula be prepared safely?

Step 1. Prepare feeding equipment:

Equipment Preparation				
Infants Under Four Months of Age		Infants Four Months of Age & Older		
	Clean & Sterilize All Feeding Equipment:1		Clean All Feeding Equipment:1	
1.	Wash hands – hands should always be washed	1.	Wash hands – hands should always be washed	
	thoroughly with soap and water, for at least 20		thoroughly with soap and water, for at least 20	
	seconds, before cleaning, sterilizing and handling		seconds, before cleaning and handling feeding	
	feeding and preparation equipment.1		and preparation equipment.1	



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	Equipment Preparation			
	Infants Under Four Months of Age	Infants Four Months of Age & Older		
	Clean & Sterilize All Feeding Equipment:1	<u>Clean</u> All Feeding Equipment: ¹		
2.	Clean feeding equipment and preparation area—wash all feeding and preparation equipment (e.g. cups, bottles, nipples, caps, tongs, can opener and spoons) in hot soapy water. ² Ensure all remaining food residue is removed prior to sterilization.	 Clean feeding equipment and preparation area—wash all feeding and preparation equipment (e.g. cups, bottles, nipples, caps, tongs, can opener and spoons) in hot soapy water.² Ensure all remaining food residue is removed. Rinse – rinse all feeding and preparation 		
3.	Rinse – rinse all feeding and preparation	equipment in clean potable water.3		
	equipment in clean potable water.3	4. If bottle(s) are not being used immediately they		
4.	Sterilize equipment—sterilize all feeding and preparation equipment. This can be done in with a dishwasher which sterilizes (NSF-184 approved) or by boiling. To sterilize by boiling: a. fill a large pot with water and put all feeding equipment in; b. cover with a lid and bring to rolling boil for two minutes; c. remove feeding equipment with sterile tongs; d. set on a clean paper towel or clean cloth to air dry.	should be fully assembled to prevent the inside of the bottle being contaminated. Cover all feeding equipment and store in a clean place until ready for use. ^{4,5}		
5.	If bottle(s) are not being used immediately they should be fully assembled to prevent the inside of the bottle being contaminated. Cover all feeding equipment and store in a clean place until ready for use. 4,5			

Step 2. Obtain safe, age appropriate water* if preparing liquid concentrate or powdered infant formula:

	Water Preparation			
Infants Under Four Months of Age		Infants Four Months of Age & Older		
St	f <u>erilize Water</u> for Liquid Concentrate and Powdered Infant Formula			
1.	Fill a large pot with cold tap water. Do not use hot tap water as it may contain more metal contaminants from the pipes such as copper or lead. ² Bring water to a rolling boil for two minutes. ²	Use water from the cold water tap. Do not use hot tap water as it may contain more metal contaminants from the pipes such as copper or lead. ²		
	Extended boiling increases the concentration of potential contaminants and minerals such as lead, therefore, is not recommended. ⁶	No other preparation is required.		



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Water Preparation		
Infants Under Four Months of Age	Infants Four Months of Age & Older	
<u>Sterilize Water</u> for Liquid Concentrate and Powdered		
Infant Formula		
3. Boiled water can be stored in a sterilized, tightly closed container for two to three days in a refrigerator, or for 24 hours at room temperature.		

For information on appropriate water choices, refer to the Nutrition Guideline: 6.1 Water.

Step 3. Prepare formula:

Ready-to-feed Infant Formula			
Infants Under Four Months of Age	Infants Four Months of Age & Older		
Wash the top of formula can with hot soapy water. Rinse with clean water.	Wash the top of formula can with hot soapy water. Rinse with clean water.		
2. Pour the formula into a sterilized bottle . Do not add water.	2. Pour the formula into a clean bottle . Do not add water.		
3. For immediate use: formula which has not been consumed within two hours should be discarded. 1,5	3. For immediate use: formula which has not been consumed within two hours should be discarded. ^{1,5}		
For later use: place formula in the refrigerator immediately. Unless otherwise indicated on the formula can, use within 48 hours.	For later use: place formula in the refrigerator immediately. Unless otherwise indicated on the formula can, use within 48 hours.		

	Liquid Concentrate Infant Formula			
Infants Under Four Months of Age		Infants Four Months of Age & Older		
1.	Rinse with clean water.	 Wash the top of formula can with hot soan water. Rinse with clean water. 	•	
2.	Pour the liquid concentrate formula into a sterilized bottle.	2. Pour the liquid concentrate formula into a bottle .	clean	
3.	Use previously boiled water that has been cooled to room or body temperature.	3. Use cold tap water.4. Follow the manufacturer's instructions for	the	
4.	Follow the manufacturer's instructions for the amount of water to be added.	amount of water to be added.5. Shake concentrate and water to mix.		
5. 6.	Shake concentrate and water to mix. For immediate use: formula which has not been consumed within two hours should be discarded. ^{1,5}	 For immediate use: formula which has no consumed within two hours should be discarded.^{1,5} 	t been	
For later use: place prepared formula in the refrigerator immediately. Prepared formula can be stored in the refrigerator for up to 24 hours. ⁷		For later use: place prepared formula in the refrigerator immediately. Prepared formula can be stored in the refrigerator for up to 24 hours. ⁷		



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	Powdered Infant Formula (PIF)			
Infants Under Four Months of Age		Infants Four Months of Age & Older		
1.	Prepare PIF for immediate use.	1.	Preferred method is to prepare PIF for	
2.	Use previously boiled water that has been cooled		immediate use.	
	to room or body temperature to reconstitute PIF.	2.	Use cold tap water to reconstitute PIF.	
3.	Pour previously boiled water into a sterilized	3.	Pour cold tap water into a clean bottle . Follow	
	bottle . Follow the manufacturer's instructions for		the manufacturer's instructions for the amount	
	the amount of water to be added.		of water to be added.	
4.		4.	Fill the measuring scoop with formula powder	
	level off using a sterilized knife. Take care to add		and level off using a knife. Take care to add	
	the correct number of scoops to the water in the		the correct number of scoops to the water in	
	bottle. Always measure the amount of powder using		the bottle. Always measure the amount of	
	the scoop provided in the can.8		powder using the scoop provided in the can.8	
5.	Shake powder and water to mix.	5.	Shake powder and water to mix.	
6.	Prepared formula which has not been consumed	6.	Prepared formula which has not been	
	within two hours should be discarded. 1,5		consumed within two hours should be	
			discarded. ^{1,5}	
		_		
For later use: see instructions below.		For later use: place prepared formula in the		
		refrigerator immediately. Prepared formula can be		
		Sto	red in the refrigerator for up to 24 hours.	

How do you prepare powdered infant formula for later use for infants under four months of age?

It is preferred to prepare formula for immediate use;⁹ however, if formula needs to be prepared ahead, previously boiled water that has been cooled to 4°C (fridge temperature) can be used to avoid the development or growth of bacteria. Pour the previously boiled, cooled water into a sterilized bottle. Follow the manufacturer's instructions for the amount of water to be added. Fill the measuring scoop with formula powder and level off using a sterilized knife. Place reconstituted formula in the refrigerator immediately. Formula prepared in this way can be stored in the refrigerator for up to 24 hours.^{1,4,5,7}

How do you prepare infant formula when away from home?

It is ideal to prepare infant formula for immediate use to limit the time for potential bacterial growth. As such, it is best to prepare formula fresh at the destination by following the instructions below. Any infant formula which has not been consumed within two hours of preparing should be thrown out.

Liquid Concentrate or Powdered Infant Formula:

Bring a clean* bottle/nipple with premeasured water. In another container bring premeasured powdered infant formula, or if using liquid concentrate – take the unopened can of formula. Mix the appropriate amount of infant formula (powder or concentrate) into the bottle and serve immediately.



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Ready-to-feed Infant Formula:

Bring a clean* bottle/nipple and the unopened formula. The ready-to-feed formula can be poured into the bottle and served immediately.

If infant formula cannot be prepared for immediate use when away from home, it should be prepared following the instructions for later use (See question above, 'How can infant formula be prepared safely? Step 3'). Prepared infant formula should be transported in a cooler bag with an ice pack.⁶ If the infant formula was transported cold and arrived at the destination within two hours, then the formula can either be provided to the infant or stored in a refrigerator for up to 24 hours.⁶ If formula is not transported in a cooler bag with an ice pack the formula must be used within two hours of preparation.^{6,7}

*sterilized if infant is under four months

Are there risks with infants consuming under or over concentrated formula?

When preparing liquid concentrate and powdered infant formula it is important to follow the instructions for proper amounts of water to add. Always use the proper amount of formula and water recommended on the formula can unless otherwise prescribed by a Registered Dietitian or pediatrician. Adding more water than recommended reduces the caloric value of the formula, which can cause protein energy malnutrition. ¹⁰ In addition to inadequate calorie consumption, consuming an abundant amount of overly dilute formula can lead to water intoxication. ¹¹ Although oral water intoxication is rare, it can result in adverse medical effects such as hyponatremic seizures. ¹¹ Adding less water than recommended can create an over concentrated formula which may result in an infant suffering from hypernatremic dehydration. ^{10,12} Infants with hypernatremic dehydration often present with minimal or generic symptoms such as diarrhea early on. The absence of clear symptoms can lead to delayed diagnosis. ¹² However, hypernatremic dehydration can result in severe complications including "seizures, cerebral edema, venous sinus thrombosis, pontine myelinolysis, permanent brain damage, disseminated intravascular coagulation, acute renal failure, and even death." ¹²

How do you warm infant formula?

- 1. Place the bottle with prepared formula in a bottle warmer or a container with hot water for no more than 15 minutes. The bottle lid/nipple should not be covered with water when being warmed as this can lead to contamination of the formula. Do not warm formula in the microwave. It can create hotspots that can scald an infant's mouth.
- 2. An appropriate temperature for the formula is between room and body temperature. Test a few drops on the inside of your wrist to check the temperature. Too cool is better than too warm.

Feed immediately and discard any formula that has not been consumed within two hours. 1,4,5

Why are the cleaning and sterilizing steps so important when preparing infant formula?

Poor hygiene and inadequately cleaned/sterilized equipment used for preparing feeds have been reported as probable causes of some bacterial outbreaks (i.e. *Cronobacter*) from powdered infant formula.^{13,14} Prior to cleaning (and sterilizing equipment for infants under four months of age), the person preparing the formula should clean the preparation surface and wash their hands with soap and water. Washing hands



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and cleaning surfaces reduces the risk of feeds becoming contaminated during preparation. *Cronobacter* has the ability to grow on surfaces (known as a biofilm) commonly used in infant feeding equipment, such as latex, silicon and stainless steel. ¹⁵ Biofilms on such equipment may result in continual contamination of feeds. ¹⁵ All infant feeding and preparation equipment (e.g. feeding cups, bottles, rings and nipples) must be thoroughly cleaned (and sterilized if the infant is under four months of age). ⁵

Why do we recommend sterilizing water to prepare infant formula for infants under four months of age?

Tap water, well water, and commercially bottled water are not sterile.² The three main types of microorganisms that can be found in drinking water are bacteria, viruses and protozoa.¹⁶ These can exist naturally or can occur as a result of contamination from human or animal waste.¹⁶ The main goal of sterilization of drinking water is to remove or kill most of these organisms.¹⁶ While it is not currently possible to completely eliminate the risk of waterborne disease, sterilization helps to reduce the risk.¹⁶ The most common manifestation of waterborne illness is gastrointestinal upset (nausea, vomiting and diarrhea), however; in susceptible individuals (such as infants) the effects may be more severe, chronic or fatal.¹⁶

Until what age does water need to be sterilized for healthy term infants?

Water used in infant feeding should be sterilized for infants less than four months of age.

There is no research supporting a specific infant age at which it is safe to stop boiling water for infant formula preparation. Age, alone, is a poor predictor of infant vulnerability to foodborne illness and immune status varies among infants.⁶ Sterilizing water for healthy term infants has historically been recommended until infants are four months of age. By four months infants are commonly putting many non-sterilized objects in their mouths. Therefore four months has been chosen as the age for discontinuing the sterilization of water.

Can you sterilize water by boiling in an electric kettle?

Water can be sterilized in an electric kettle without an automatic shut-off. Kettles with an automatic shut-off should not be used as they turn off once the water comes to a boil and will not allow water to be at a rolling boil for two minutes.

What is the recommended way to store prepared infant formula?

It is preferred to prepare formula for immediate use, however, if formula needs to be prepared ahead, an option for preparation for later use is provided. Feeds should be stored in a refrigerator immediately after preparation.⁴ Refrigerators should remain at \leq 4°C to prevent or slow down growth of harmful bacteria.⁵ When feeds are stored at \leq 4°C, bacteria growth is considerably less than when feeds are stored at higher temperatures.

Infant formula should not be held in the refrigerator door as this section has been found to have higher temperatures than shelves in a refrigerator.⁷ The temperature of the refrigerator should be monitored daily with a digital thermometer.



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What are the warming and holding time recommendations for infant formula?

Infant formula should be prepared for immediate use. If it is not possible to prepare for immediate use infant formula prepared earlier and stored in the refrigerator should be removed from the refrigerator just prior to feeding to decrease the risk of bacteria growth. Warming formula can be done with a bottle warmer or by placing the bottle in a container of warm water. Formula should be warmed for no more than 15 minutes as many bacteria, including *Cronobacter*, can grow rapidly in warm temperatures (6 to 47°C). Since 15,17,18 Caregivers should swirl the formula in the bottle and check the temperature on the inside of their wrist to prevent hotspots and to ensure that the formula is not too hot for the infant. Once warmed, the formula should be fed immediately. Any infant formula that is not consumed within two hours should be discarded (even if the infant was not able to consume any of it but it had sat out at room temperature). Leftovers should never be reheated, refrigerated or saved for next feed. Increased feeding times are generally associated with increased risk due to possible bacterial growth. Holding prepared feeds at temperatures >4°C for extended periods provides an opportunity for such bacteria to grow.

Is liquid infant formula more expensive than powdered infant formula?

The costs for liquid concentrate and powdered infant formula are comparable for 100 mL of prepared formula. However, upfront costs for liquid concentrate are higher, as it is sold by the case rather than individual cans. An additional barrier for liquid concentrate may be transporting the case home (via walking, bus, etc). When barriers, including cost, do not permit the use of liquid formula, education and focus must be placed on the safe preparation and handling of powdered infant formula.

Can bottled water be used to prepare infant formula?

Commercially bottled water (excluding carbonated and mineral water) can be used to prepare infant formula.⁶ However, bottled water is not sterile and therefore must be boiled (to sterilize) until an infant is four months of age.¹⁹

What is the safest way to prepare powdered formula when away from home?

If formula needs to be prepared away from home, pre-measured (and sterilized for infants under four months of age) water and pre-measured formula powder should be brought separately and mixed immediately before feeding. Any prepared formula which has not been consumed within two hours should be discarded 1,4,5

Can a dishwasher be used to sterilize feeding equipment?

Dishwashers which are NSF-184 approved can be used on the sanitizing cycle to sterilize feeding equipment.²⁰ This information is typically found on the top, inside of the dishwasher door. Contact your local public health inspector if you have questions about sterilization methods.



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Can plastic bottles or nipples be sterilized by boiling?

Many of the bottles and nipples on the market have been designed to withstand boiling, however, some may not. Refer to the manufacture information to determine if the bottles/nipples can be boiled. Some products may withstand boiling after every use, even if the product recommends only boiling prior to the first use. Caregivers should call the product manufactures information line if they are unsure if their bottles or nipples can be sterilized by boiling. Do not use bottles or nipples which warp, melt, or become sticky / gummy when boiled.

Does a thermometer need to be used even when a fridge has a dial?

Yes, a thermometer is needed to ensure a refrigerator remains at ≤4°C.⁷ A refrigerator dial controls the temperature in a refrigerator but dial numbers/level do not correlate to a specific temperature. Only a thermometer can provide the accurate temperature of a refrigerator.

How should cans of powdered infant formula be stored?

PIF should be stored in a cool, dry place (not in the refrigerator) with the lid tightly closed. The scoop should be dry before placing back in the can. The date that PIF is opened should be recorded on the lid. PIF should be used within one month of opening. PIF which is passed the expiry date should not be used.

How should open cans or tetra-packs of liquid formula (ready-to-feed or concentrate) be stored?

Unless directions on the formula can state otherwise, open cans of liquid formula should be covered with clear plastic food wrap and placed in the refrigerator. The date the can is opened should be written on the can and used within 48 hours of opening. Liquid formula which is passed the expiry date should not be used.

Are antibacterial soaps or special cleaning products needed to wash feeding equipment?

No, feeding equipment can be washed with regular dish soap and hot water to remove residue. For infants less than four months of age, equipment should be sterilized in a pot with boiling water for two minutes.²

Are there any handouts on safe preparation and handling of infant formula that I can use with my clients?

For infant nutrition resources visit Nutrition Education Materials at http://www.albertahealthservices.ca/nutrition/Page11115.aspx and click on **Infants.**

For more information related to healthy infants and children see Healthy Parents Healthy Children.



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